EUROPEAN
COMMISSION

Brussels, 22.5.2014
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COMMISSION IMPLEMENTING DECISION

of 22.5.2014

amending the marketing authorisation granted by Decision C(2000)1407 for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10 and 28 thereof,

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2],

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Merck Sharp & Dohme Limited in accordance with Regulation (EC) No 1234/2008 and in accordance with Article 61(3) of Directive 2001/83/EC,

Having regard to the opinion of the European Medicines Agency, formulated on 20 March 2014 by the Committee for Medicinal Products for Human Use on the periodic safety update report for this medicinal product,

Having regard to the opinions of the European Medicines Agency, formulated on 21 November 2013 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The placing on the market of the medicinal product "PegIntron - Peginterferon alfa-2b" was authorised by Commission Decision C(2000)1407 of 25 May 2000.

(2) The marketing authorisation holder submitted a periodic safety update report for this medicinal product. This report was assessed by the Pharmacovigilance Risk Assessment Committee as to whether the marketing authorisation(s) concerned should be maintained, varied, suspended or withdrawn.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 334, 12.12.2008, p. 7.
[3] OJ L 311, 28.11.2001, p. 67.

(3) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex IV to this Decision, shows that a decision should be taken amending the marketing authorisation for the medicinal product concerned.

(4) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(5) Decision C(2000)1407 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(6) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2000)1407 should therefore be replaced.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom.

Done at Brussels, 22.5.2014

For the Commission
Paola TESTORI COGGI
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION